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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,183	06/19/2001	Bret S. Weinstein	15915	2814

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EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT	PAPER NUMBER
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1632

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/884,183

Applicant(s)

WEINSTEIN, BRET S.

Examiner

Marcia S. Noble

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 6 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 6, 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/2006 has been entered.

Preliminary Matters

2. The instant applicant has been transferred to a new Examiner. The new Examiner is Marcia Noble.

Status of Claims

3. Claims 5, 6, and 21-23 are pending. Claim 5 is amended and claims 21-23 are added by amendment filed 11/16/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 5 and 6, rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (Nature 329:669-674, April 1998), have been amended and are no longer anticipated by Lee et al. Therefore the rejection is withdrawn.

Claim 5 was amended to specify that only a subset of the first population having telomere lengths of greater or less than a median telomere length are permitted to produce offspring. Lee et al does not teach this limitation. Therefore, the rejection is withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 5, 6, and 21-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

The claims are directed to methods of breeding an animal line for experimental use, comprising preselecting a first population of animals that comprise telomeres of determinable lengths, determining a statistical distribution of telomere lengths and permitting only animals with telomere lengths greater than or less than the median telomere length to produce offspring (claim 5 and 21-23). Claim 6 further specifies that in the second population produced by breeding the subset of the first population, the statistical distribution of telomere length among the animal of said second population is modified compared to the distribution among the animal of said first population.

The instant specification has contemplated that introduction of a desirable distribution of telomere lengths in a breeding population of animals will produce a model animals better suited for testing agents (p. 3, last par). The instant specification asserts that a consequence of ultra-long telomeres results in more tumors (p. 3, lines 7 and 8). The instant specification has purported that a fixed optimum target for telomere length can be set in order to produce model organisms better suited to illuminate dangers of one of two opposing types carcinogenic effects and tissue damage/accelerated aging. The instant specification has asserted that testing agents on two populations will provide better total resolution than testing agents on a single population (p. 3).

However, the evidence of record does not provide a correlation between optimization of telomere lengths and any disease or disorder. The specification has taught an observation that mice that have ultra-long telomeres seem to grow more tumors. However, the specification provides no evidence of a causative relationship. Therefore, because no causal relationship has been demonstrated between telomere length and a disease or disorder. The instantly asserted utility is not specific, real world, or substantial.

Since the evidence of record has not provided a correlation between telomere lengths and any disease or disorder, the utility of optimizing telomere length in a population of animals is not apparent. The evidence of record has not provided any other utilities for the methods embraced by the claims that are specific, substantial, and credible.

It is acknowledged that the previous examiner withdrew the previous utility rejection made in the Non-Final Office Action, mailed 12/18/2003. In the Final rejection, mailed 9/23/2004, it states (p 2, last par), "Applicant's arguments have been fully considered and found persuasive. Specifically, Applicants have asserted a utility to provide animal lines with defined telomere length, which is supported by the instant specification. Given the art of record, the instantly claimed method should result in an animal line with a defined telomere length. It is noted that the specification fails to establish a specific correlation between any telomere length and any specific disorder as set forth in the basis of the rejection, and that there is question raised by the art of record to use of the resulting animal line." The present examiner does not agree with the previous examiner that the asserted utility of providing animal lines with defined telomere length is a specific utility because as previously stated by the previous examiners no specific correlation between any telomere length and any specific condition has been made.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

6. Claims 5, 6, and 21-23 also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The claims are directed to methods of breeding an animal line for experimental use, comprising preselecting a first population of animals that comprise telomeres of determinable lengths, determining a statistical distribution of telomere lengths and permitting only animals with telomere lengths greater than or less than the median telomere length to produce offspring (claim 5 and 21-23). Claim 6 further specifies that in the second population produced by breeding the subset of the first population, the statistical distribution of telomere length among the animal of said second population is modified compared to the distribution among the animal of said first population.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The instant invention assumes that breeding is the only factor controlling telomere length. However, the instant specification provides no causative or correlative relationship between breeding and its impact on telomere length. As previously noted by the previous examiner in the Final action, mailed 7/14/2006 (p. 4, last par), "As noted previously, at the time of filing and today there exists multiple lines of inbred animals (mice, dogs, cats, cattle,...) and while the skilled artisan would acknowledge that there are phenotypic differences among various lines, none of the phenotypes are correlated with telomere length (for example the predisposition of one line of mice to diabetes or susceptibility to carcinogens). To the contrary rather than telomere length, other genotypic factors are important in determining the phenotype of a given animal (see for example review of Festing (Neurobiology 20:23-244, 1999)). Moreover, it is further noted that this is consistent with Applicant's own views that it is not telomere length by itself that may affect a phenotype, rather the mechanisms that control it (see Weinstein et al., Exp Gerontol. (2002 May) 37(5):615-27), and that the breeding of favorable phenotypes in laboratory animals may result in this loss of control not a consequence of telomere length itself." Therefore, because the art of telomeres and factors controlling telomere length are rudimentary and contains many unknown factors, and the

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specification provides no evidence beyond what is taught in the art, an artisan would not know if the claims method would provide an animal with determined telomere lengths as intended because the art and specification do not teach the factors controlling telomere length.

New Matter

7. Claims 5, 6, and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claim 5 recites "permitting only a subset of the first population having telomere lengths greater than a median telomere length or a subset of the first population having telomere lengths less than a median telomere length". The specification does not provide literal support for this recitation. Newly added claim 23 recites, "the subset comprising animals with telomere lengths outside of a predetermined range or telomere length". The specification does not provide literal support for this recitation as well. The specification teaches that changes in telomere length can be produced by restricting or eliminating the fitness of individuals in the breeding pool that have telomere length outside of an optimal range (p. 5, lines 8-10). However, the specification never suggests that the median is an optimal or

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predetermined range. Therefore, the specification does not provide figurative support as well. Therefore, an artisan would not know what the predetermined range is or if the median would fit the criterion of an optimum range.

In Applicant's remark, filed 11/16/2006, Applicant asserts that the amendments to the claims are supported by the specification on page 5 and 6. However, as discussed above, it is not clear what aspect of pages 5 and 6 Applicant considered supportive of the instant amendment and new claims.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites, "such that the statistical distribution of telomere length among the animals of said second population **is modified**". However, the metes and bound of this recitation are unclear because it is not clear how the statistical distribution is to be modified. It seems that some essential step in the process of modifying the distribution are missing.

Claim 6 also recites, "animals of said first population". The metes and bounds of this recitation are indefinite because it is not clear if this recitation refers to the

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preselected first population in line 3 of claim 5, or the subset of the first population in line 9 of claim 5.

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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